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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/133,766	08/12/1998	BIRGIT ANNA HELM	HELM-ET-ALPC	6988

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	32

DATE MAILED: 05/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/133,766	Helm et al.
Examiner	**Art Unit**
Ron Schwadron, Ph.D.	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *44 and 47-54* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *44 and 47-54* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. *08/446,760*.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Claims 44,47-54 are under consideration. Claims 45,46 have been canceled. Claim 54 is newly added.

RESPONSE TO APPLICANTS ARGUMENTS

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 54 and 47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the method of claim 54. Regarding applicants comments about page 12 of the specification and Table 2, said Table refers to a particular tested clone and 5-HT release. The amounts of mediator release disclosed on page 12 refer to an empirical score in a particular experiment wherein each score is a discrete quantity. Furthermore, Table 2 and page 12 of the specification indicate an experimental protocol wherein release of 5-HT by a particular clone is to be measured, it does not disclose what results were obtained. There is no support in the specification as originally filed for the scope of the claimed invention (eg. the claimed invention constitutes new matter).

There is no support in the specification as originally filed for the method of claim 47. While the specification discloses use of a "high secretor variant", it does not disclose use of any variant per se. While the term "high secretor variant" is indefinite, it at least implies that there is some difference between a "high secretor variant" and a variant per se (wherein the indefiniteness arises from a lack of quantitative definition of said term). There is no support in the specification

as originally filed for the scope of the claimed invention (eg. the claimed invention constitutes new matter).

4. Claims 44,47-54 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants arguments have been considered and deemed not persuasive.

The specification is not enabling for the claimed method. Benyon et al. teach that a variety of self proteins and other molecules which are not allergens (eg. compound 48/80, poly-L-lysine, substance P, VIP, somatostatin (see page 898, second column)) cause the release of the mediator histamine from mast cells. Said substances are not allergens. In fact, Benyon et al. refer to the release of histamine by mast cells in response to the aforementioned substances as cause by "non-immunological stimuli". While Benyon et al. also disclose that specific different specific mediators are released by IgE versus IgE independent mast cell activation, the instant claims do not recite release of any particular mediator. Thus, the claimed invention could not be used to determine the allergenicity of a substance because nonallergens also cause the release of mediators from mast cells. In fact, Benyon et al. disclose that nonallergens can cause the release of histamine from mast cells in similar amounts to that seen when allergens are used in the assay. The claimed invention encompasses a method wherein histamine is the only mediator assayed (eg. see claim 50). Furthermore, if the agent causes release of mediators from mast cells in the absence of IgE, using the assays disclosed in the specification it would not be possible to determine if the agent was an allergen per se (eg. capable of inducing IgE antibodies) because the agent causes release of mediators from mast cells in the absence of IgE. Therefore, the specification is not enabling for the claimed invention.

Regarding applicants comments, Benyon et al. teach that a variety of self proteins and other molecules which are not allergens (eg. compound 48/80, poly-L-lysine, substance P, VIP, somatostatin (see page 898, second column)) cause the release of the mediator histamine from mast cells. Said substances are not allergens. Thus, based on the teachings of Benton et al., histamine release in itself does not indicate that a substance will also cause IgE mediated allergic reactions. In fact, Benyon et al. refer to the release of histamine by mast cells in response to the aforementioned substances as cause by "non-immunological stimuli". While Benyon et al. also disclose that specific different specific mediators are released by IgE versus IgE independent mast

cell activation, the instant claims do not recite release of any particular mediator. Thus, the claimed invention could not be used to determine the allergenicity of a substance because nonallergens also cause the release of mediators from mast cells. In fact, Benyon et al. disclose that nonallergens can cause the release of histamine from mast cells in similar amounts to that seen when allergens are used in the assay. The claimed invention encompasses a method wherein histamine is the only mediator assayed (eg. see claim 50). Furthermore, if the agent causes release of mediators from mast cells in the absence of IgE, using the assays disclosed in the specification it would not be possible to determine if the agent was an allergen per se (eg. capable of inducing IgE antibodies) because the agent causes release of mediators from mast cells in the absence of IgE. Applicant has made various statements regarding what is known in the art or experimental results that have been obtained . The MPEP section 716.01© (Rev. 1, Feb 2003)) discloses that:

ATTORNEY ARGUMENTS CANNOT TAKE THE PLACE OF EVIDENCE

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 44,47-54 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 44 is indefinite in the recitation of "sensitizing agent" because it is unclear what this term means or encompasses. While the specification discloses a specific example of a sensitizing agent (IgE which binds a particular allergen), it is unclear as to what other agents would or would not constitute a sensitizing agent. This term is not defined in the specification and it has no art recognized meaning.

Regarding applicants comments, page 3 of the specification refers to IgE which binds a particular allergen. Page 4 of the specification refers to human serum containing IgE, IgE or a "functional equivalent thereof". There is no disclosure in the specification as to what a functional equivalent of IgE means or encompasses. Thus, while the specification discloses a specific example of a sensitizing agent (IgE which binds a particular allergen), it is unclear as to what other agents would or would not constitute a sensitizing agent. This term is not defined in the specification and it has no art recognized meaning.

7. No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1900~~ 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644